

Application S/No. 10/827,133
Response to Office Action
dated July 28, 2006

Docket No. 6704-29

RECEIVED
CENTRAL FAX CENTER

NOV 27 2006

REMARKSStatus of the Application

Claims 1-4, 6, 9-11, 15, 16, 18-23, 25, 26, 30 and 31 were pending in the application at the time the Office Action was mailed. Claims 1, 3, 9, 15, 16, 18-23, 25, 26, and 30 were allowed. Claims 2, 4, 6, 10, 11, and 31 were rejected.

In this reply, claims 2, 4, and 10 have been amended; claims 6, 11, and 31 have been canceled; and no new claims have been added. Therefore, claims 1-4, 9, 10, 15, 16, 18-23, 25, 26, and 30, as amended, are pending. Consideration of these claims is respectfully requested.

Rejection Under 35 U.S.C. 112 ¶2

Claims 2, 6, 10, 11, and 31 were rejected under the second paragraph of 35 USC 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although applicants do not necessarily agree or acquiesce in these rejections, each of the claims rejected under this section has either been amended or canceled in order to expedite allowance of the present application. In particular, claims 2 and 10 have been amended as suggested by the examiner, and claims 6, 11, and 31 have been canceled.

Application S/No. 10/827,133
Response to Office Action
dated July 28, 2006

Docket No. 6704-29

Rejection Under 35 U.S.C. 112 ¶1- Written Description

Claims 2, 4, and 10 were rejected under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement. More specifically, the examiner maintained the rejection of claim 4, as set forth in the Office Action of February 10, 2006. According to the examiner:

The specification teaches that the *LucCDABE* operon contains five genes necessary for self-sustained bioluminescence in bacteria: *LuxAB* is a luciferase, which catalyzes the light-producing reaction; *LuxCE* is a multi-component enzyme that converts myristic acid to a fatty aldehyde substrate for the light-producing reaction; and *LuxD* is a transferase that assists *LuxCE* (e.g., paragraph bridging pages 5-6). The specification teaches nucleic acid constructs comprising *luxA* and *luxB* genes in addition to *luxC*, *luxD*, and *luxE* genes (e.g., page 16, lines 22-27). Claim 4 reads on embodiments where the nucleic acid construct comprises *luxA*, *luxC*, *luxD*, and *luxE* genes, or a construct comprising *luxB*, *luxC*, *luxD*, and *luxE* genes. These combinations are not supported by the specification, claims or drawings as originally filed in that the specification teaches that both *luxA* and *luxB* are required in addition to the *luxC*, *luxD* and *luxE* genes for all proteins necessary for production of bioluminescence without addition of an exogenous substrate. The response does not point to portions of the specification, claims or drawings as originally filed as support for the amendment of Claim 4. Therefore, Claim 4 represents a departure from the specification, claims and drawings as originally filed.

Although, applicants' arguments presented in the paper dated May 10, 2006 were considered, according to the examiner, the claims still require the combination of *LuxA*, *LuxC*, *LuxD*, and *LuxE*, or the combination of *LuxB*, *LuxC*, *LuxD*, and *LuxE*, which are not supported by the specification, as originally filed.

Claim 4 has been amended to recite: "[t]he purified nucleic acid construct of claim 1, wherein the gene cassette encodes the modified *Lux A*, the modified *LuxB*, *LuxC*, *LuxD*, and *LuxE*." Claim 4 now requires that all five *lux* genes be included in the construct.

WPB:263944:1

Application S/No. 10/827,133
Response to Office Action
dated July 28, 2006

Docket No. 6704-29

Rejection Under 35 U.S.C. 112 ¶1 - Enablement

Claims 2 and 10 were rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. According to the examiner:

Claims 2 and 10 could not be considered to be enabled by the instant specification as the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, a skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. More specifically, Claims 2 and 10 were rejected under the first paragraph of 35 USC 112 because the specification does not teach how to make and use a nucleic acid encoding a modified LuxB protein comprising a carboxy terminal sequence that specifically binds to a tail-specific protease, resulting in a decreased half-life in an E. coli cell relative to a wild-type LuxB protein in an E. coli cell.

The working examples of the specification clearly demonstrate that the addition of a tail-specific protease sequence to the C-terminus of the LuxB protein does not alter the half-life of the protein in an *E. coli* cell (e.g. pages 15-16). The response did not provide evidence that the claimed modification of the encoded LuxB protein results in the claimed reduction in half-life.

Claims 2 and 10 have herewith been amended to indicate that the modified LuxB comprises "a PEST sequence in its carboxy terminus that specifically binds to a protein associated with a ubiquitin-proteasome pathway." This is described in Examples 4 and 5 of the specification.

Conclusion

The currently pending claims before the examiner are supported throughout the specification and are patentable over the prior art. No new matter has been added. This

Application S/No. 10/827,133
Response to Office Action
dated July 28, 2006

Docket No. 6704-29

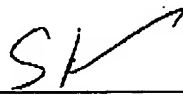
application is now in full condition for allowance, and such action is respectfully requested.

This paper is accompanied by a petition for a one month retroactive extension of time. The Commissioner is hereby authorized to charge the fee for the petition and any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-3110.

The examiner is cordially invited to call the undersigned if clarification is needed on any matter within this amendment, or if the examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Date: November 27, 2006


Stanley A. Kim, Ph.D., Esq.
Registration No. 42,730
RUDEN McCLOSKEY, SMITH,
SCHUSTER & RUSSELL, P.A.
222 Lakeview Avenue
Suite 800
West Palm Beach, FL 33401-6112
Telephone: (561) 838-4500
Facsimile: (561) 514-3412